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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,760	Applicant(s) FABRIES, LIONEL
	Examiner QIUWEN MI	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 August 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7,9,-11, 13, and 14 is/are rejected.
- 7) Claim(s) 12 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/1668)
 Paper No(s)/Mail Date 7/24/06
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of species "diethylene glycol monoethyl ether" from Claim 3; "reconstituted synthetic AGPI's or natural extracts" from Claim 6; "anti-inflammatory" from Claim 7; "bisabolol" from Claim 9; "polyvinyl pyrrolidone" from Claim 10; "neem seed oil" from Claim 11; and "coated or non-coated silica microreservoirs present in the formulation with a concentration ranging from 2 to 10%" in Claim 14" in the reply filed on 8/27/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, in the restriction requirement, Applicant is required to elect one species from each group,

Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-14 are pending. Claims 1-7, and 9-14 are examined on the merits.

The election of species requirement for claims 3, 6, 10, 11, and 14 are withdrawn.

Claim Objections

Claim 12 is objected to because it is dependent upon claim 1, which is being rejected.

Claims 5, 6, 11, and 12 are objected to because of the following informalities:

Claim 5 recites "wherein the fatty acids are chosen from a group consisting of hemp oils" (lines 1-2). However, there is only one component in the group, Applicant is suggested to recite "wherein the fatty acids are obtained from hemp oils".

Claim 6 recites "wherein the fatty acids are added using products chosen from a group consisting of:". The recitation of "added using products" is not redundant. Applicant is suggested to recite "wherein the fatty acids are chosen from a group consisting of:".

Claim 6 recites "reconstituted synthetic AGPI's" (line 8), Applicant is required to spell out the abbreviation.

Claim 6 recites "Sesamum indicum" (line 7); and "Eicopentaenoic acid" (line 9); Claim 11 recites "Pyrethrum album" (line 4); Claim 12 recites "Rosamarius Officinalis" (line 2); and "Lavendula Hybrida", and the spellings are incorrect. The correct spellings should be "Sesamum indicum"; "Eicosapentaenoic acid"; "Pyrethrum album"; "Rosmarium Officinalis"; and "Lavandula Hybrida".

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "2-pyrrolidone, including N-methyl pyrrolidone" (line 6); Claim 6 recites "fish oil (orange roughy)" (line 3), "borage oil (Borago Officinalis)" (line 4); "coconut oil (Cocos Nucifera)" (line 5); "olive oil (Olea Europea)" (line 12); "anchusa oil (Echium

plantagineum" (line 16); Claim 10 recites "acrylic derivatives such as methacrylates and others (lines 6-7); Claim 11 recites "castor oil (*Ricinus Communis*)" (line 3); "pyrethrum and derivatives (*Pyrethrum album*), and oil garlic (*Allium sativum*)" (lines 4-5); Claim 12 recites "neem seed extract (*Azadirachta Indica*)" (line 7). Regarding the parenthetical expression, the metes and bounds of the claims are rendered vague and indefinite by the parenthetical recitation because it is unclear as to whether the limitation is part of the instantly claimed subject matter. The phrase "such as" or "including" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The phrase "derivatives" is unclear. It is unclear what modifications of acrylic and pyrethrum would be encompassed in the "acrylic derivatives" and "pyrethrum derivatives". Does it include any modification, resulting in any structure or does it include only those modifications that retain the activity of the original compound? What activity would have to be retained? Thus, it is unclear what modifications and derivatives are encompassed by the claimed "acrylic derivatives" and "pyrethrum derivatives".

Claim 13 recites "the active ingredients" in line 2, and there is insufficient antecedent basis for the limitation. It is not clear what active ingredients Applicant is referring to.

Claim 5 recites "in a proportion of 1-15%" (line 2); Claim 6 recites "in a proportion of 3 to 50%, and preferably 5% to 10%" (lines 16-17); Claim 9 recites "in a proportion of 0.01 to 10%" (line 4); Claim 12 recites "0.25% of azadirachtin" (line 7); Claim 14 recites "2-10%" (lines 3-4); "4-12%" (line 5); "2-10" (line 6); "10 to 20%" (line 8). It is not clear whether the percentage is based on weight (w/w) percentage or volume (v/v) percentage of the total composition.

Claim 12 recites "a film-forming means being a thickening, stabilizing crystallization-inhibiting agent, an antioxidant means, and an anti-inflammatory means" (lines 9-11). It is not clear what Applicant is referring to by "means". Does Applicant mean "a film-forming agent with thickening, stabilizing, and crystallization-inhibiting functions, an antioxidant, and an anti-inflammatory agent"?

Claim 6 recites "natural extract" (line 8); Claim 9 recites "natural or synthetic azulene" (line 3). The term "natural" is a relative term which renders the claim indefinite. The term "natural" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Thus, the metes and bounds of claims are rendered uncertain by the phrase "natural" in the claims because "natural" could be a relative term.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, and 10 are rejected under 35 USC § 102 (b) as being anticipated by Braun (US 5,972,360).

Braun teaches a composition comprising ethoxydiglycol (thus a solvent), polysorbate 20 (the same as Polyoxyethylene (20) sorbitan monolaurate, thus a polyoxyethylene sorbitan ester), propylene glycol (thus a solvent), fragrance oil, and tea tree oil (thus a complex of essential oil), etc (col 3, Example).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as dermo-cosmetic composition using capacity of sebaceous glands to store active ingredients and to release the ingredients through a sebum. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 1.

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1-4, 6, 7, and 10 are rejected under 35 USC § 102 (e) as being anticipated by Pinnell (US 6,524,599).

Pinnell teaches a composition comprising glycerin (the same as glycerol, thus a thickening agent), ethocydiglycol (thus a solvent), grape seed oil, sunflower seed oil (thus contains omega 6 fatty acid), sesame oil, soybean oil (thus contains polyunsaturated essential fatty acid, both omega 3 and omega 6), geranium oil, rose oil (thus an anti-inflammatory agent), chamomile oil (thus a complex of essential oil), propylene glycol, and alpha tocopherol (col 7, Example 2).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as dermo-cosmetic composition using capacity of sebaceous glands to store active ingredients and to release the ingredients through a sebum. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 1.

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1-3, and 9 are rejected under 35 USC § 102 (b) as being anticipated by Menzel et al (US 6007,796).

Menzel et al teach a composition comprising 1% calendula oil (thus an anti-inflammatory agent), babassu oil (thus an anti-inflammatory agent) (thus a complex of essential oil), 0.1% allantoin, 0.2% Aloe vera gel (thus an anti-inflammatory agent), diethylene glycol (thus a solvent), (col 4, Example 2).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be

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precluded for use as dermo-cosmetic composition using capacity of sebaceous glands to store active ingredients and to release the ingredients through a sebum. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 1.

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1, 13, and 14 are rejected under 35 USC § 102 (b) as being anticipated by Noda et al (US 4,024,223).

Noda et al teach 3.0 parts of beta-cyclodextrin (thus has the intrinsic properties of extended release, thus a delay formula) (thus falls into the claimed range of 2-10%) and 96.7 parts of water (thus a solvent) were placed in a stirrer, and stirred to form an aqueous solution. To the solution was added 0.3 part of an antiphlogistic and analgetic drug consisting of 24% methyl salicylate, 24% menthol, 36% peppermint oil, 14% camphor and 2% thymol (thus a complex of essential oil), and the mixture was stirred for 4 hours (col 7, Example 3). Noda et al also teach it has a wet packing effect for prolonged periods (thus a delay formula) (col 1, lines7-12).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as dermo-cosmetic composition using capacity of sebaceous glands to store active ingredients and to release the ingredients through a sebum. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 1.

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1, and 5 are rejected under 35 USC § 102 (b) as being anticipated by Pierce et al (US 6,063,369).

Pierce et al teach a skin care composition comprising botanicals oil (thus a complex of essential oil), water (thus a solvent), 0.01-10% quarternized hemp seed oil (thus falls into the claimed range of 1-15%), thickener etc (col 8, Table 7). Pierce et al also teaches a cream or lotion rich in essential fatty acids can help replenish skin cells damaged by the environment, i.e. sun, dryness, or surfactant damage. Hemp seed oil is high in essential omega-3 and omega-6 fatty acids, such as linoleic and linolenic acid (col 8, lines 8-15).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that the prior art product must not be precluded for use as dermo-cosmetic composition using capacity of sebaceous glands to store active ingredients and to release the ingredients through a sebum. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 1.

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1, 3, 10, and 11 are rejected under 35 USC § 102 (b) as being anticipated by Murakado et al (US 6,203,804).

Murakado et al teach a skin care composition comprising glycerol (thus a thickening agent), water (thus a solvent), 1-menthol, peppermint oil (thus a complex of essential oil) and ethanol (thus a solvent) (Table 2). Murakado et al also teach a skin care composition comprising a cooling agent selected from menthols, camphor, and bornecols (claim 1)

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that the prior art product must not be precluded for use as dermo-cosmetic composition using capacity of sebaceous glands to store active ingredients and to release the ingredients through a sebum. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 1.

Therefore, the reference is deemed to anticipate the instant claim above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Pinnell (US 6,524,599), Pierce et al (US 6,063,369), Murakado et al (US 6,203,804), and Epstein (US 5,885,593).

Pinnell teaches a skin care composition comprising glycerin (the same as glycerol, thus a thickening agent), ethocydiglycol (thus a solvent), grape seed oil, sunflower seed oil (thus contains omega 6 fatty acid), sesame oil, soybean oil (thus contains polyunsaturated essential fatty acid, both omega 3 and omega 6), geranium oil, rose oil, chamomile oil (thus a complex of essential oil), propylene glycol, and alpha tocopherol (thus a soothing agent) (col 7, Example 2). Pinnell teaches another skin care composition comprising 0.5% alpha bisabolol, 5% Aloe vera extract, (thus anti-inflammatory agents) glycerin, ethoxydiglycol, water etc.

Pinnell does not teach the incorporation of hemp seed oil, menthols, camphor, and beta-cyclodextrin into a composition.

Pierce et al teach a skin care composition comprising botanicals oil (thus a complex of essential oil), water (thus a solvent), quarternized hemp seed oil, thickener etc (col 8, Table 7). Pinnell also teaches a cream or lotion rich in essential fatty acids can help replenish skin cells damaged by the environment, i.e. sun, dryness, or surfactant damage. Hemp seed oil is high in essential omega-3 and omega-6 fatty acids, such as linoleic and linolenic acid (col 8, lines 8-15).

Murakado et al teach a skin care composition comprising a cooling agent selected from menthols, camphor, and borneols (claim 1). Murakado et al teach a skin care composition comprising glycerol, water, 1-methol, peppermint oil, and ethanol (Table 2).

Epstein teaches a skin care composition comprising 3.5% beta-cyclodextrin (thus has the intrinsic properties of extended release), water, glycerin, etc (col 6, Table).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been

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individually taught in the prior art." *In re Chekhovian*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for skin care. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for skin care.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for skin care. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.);

see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have the ability for skin care, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Pinnell, Pierce et al, Murakado et

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al, and Epstein since all of them teach compositions for skin care individually in the art. Since all the compositions yielded beneficial results for skin care, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of the components in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as dermo-cosmetic composition using capacity of sebaceous glands to store active ingredients and to release the ingredients through a sebum. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of claim 1.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655